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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/767,637 | 01/29/2004 | Michael D. Mason | 2731/103 | 5420 |
| 2101 | 7590 | 07/14/2006 | EXAMINER | |
| BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618 | | | REIMERS, ANNETTE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,637

Applicant(s)

MASON, MICHAEL D.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Müller-Lierheim (US Patent Number 4,828,563).

Müller-Lierheim discloses a method for fusing a first vertebra to a second adjacent vertebra comprising providing an implant comprising a body having first and second opposite surfaces (see figure), wherein each of the surfaces includes a plurality of protruding members, 2, for securing the body to an adjacent vertebra, each protruding member of the implant characterized by a member longitudinal axis, each member having a profile perpendicular to the member's longitudinal axis that includes a generally arcuate portion that encompasses more than one hundred and eighty degrees of curvature as measured from the center of curvature, and each of the surfaces and protruding members includes a bioactive coating, 4 (see figure and column 1, lines 50-55). In addition, each member is disposed about an axis of symmetry lying on the corresponding surface such that each member protrudes beyond the height of the corresponding surface along the axis of symmetry (see figure).

The method further includes forming at least one keyway in the first vertebra corresponding to each of the at least one protruding members on the first surface and at least one keyway in the second vertebra corresponding to each of the at least one protruding members on the second surface, wherein each keyway is characterized by a keyway longitudinal axis and has a profile perpendicular to the keyway's longitudinal axis including a generally arcuate portion that encompasses more than one hundred and eighty degrees of curvature as measured from the center of curvature; and inserting the implant between the first vertebrae and the second vertebra in a manner so that each protruding member slides into the corresponding keyway, such that movement between the implant and first vertebra along any perpendicular to the longitudinal axis of the at least one keyway in the first vertebra is prevented (see figure and column 1, lines 28-49, column 3, lines 1-6 and 31-39). From the previously cited passages, i.e. column 1, lines 28-49 and column 3, lines 1-6 and 31-39, it is apparent that keyways will be formed in the vertebra to correspond to the protruding members either through the surgeon actually forming the keyways in the vertebra or keyways being formed by bone ingrowth once the implant is placed against bony tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Kenna (EPO 0421485).

Kenna discloses a method for fusing a first vertebra to a second adjacent vertebra comprising providing an implant comprising a body having first and second opposite surfaces (see figures 2-3), wherein each of the surfaces includes a protruding member, 5, for securing the body to an adjacent vertebra and each of the surfaces and protruding members includes a bioactive coating, 7 (see figures 1-4). In addition, each member is disposed about an axis of symmetry lying on the corresponding surface such that each member protrudes beyond the height of the corresponding surface along the axis of symmetry (see figures 2-3).

The method further includes forming a keyway in the first vertebra corresponding to each of the at least one protruding members on the first surface and at least one keyway in the second vertebra corresponding to each of the protruding members on the second surface, the keyways shaped to securely receive the protruding members; and inserting the implant between the first vertebrae and the second vertebra in a manner so that each protruding member slides into the corresponding keyway, such that fusion of the vertebrae is achieved without a bone graft (see figure 4 and column 4, lines 21-22, and column 6, lines 4-17).

Kenna discloses the claimed method except for having a plurality of protruding members with corresponding keyways. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant device of Kenna having a plurality of protruding members with two corresponding

Art Unit: 3733

keyways, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding claim 6 have been fully considered but they are not persuasive. Examiner understands applicant's explanations regarding the use of multiple members and keyways. However, the use of multiple members and keyways is not novel (see Marnay US Patent Number 5,314,477 figure 1 and column 6, lines 39-57). Furthermore, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., such multiple members and keyways take advantage of characteristics of bone to achieve better mechanical fixation of the implant with the vertebrae. Cortical bone, which is at the periphery of a bone, is denser and better able to support a mechanically rigid coupling to the implant. The multiple members of the implant, rather than a single member, lead to implantation in this cortical bone) are not recited in the rejected claim(s). Although the Declaration from Dr. Mason has been considered, limitations from the Declaration are not read into the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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